

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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|--|--|--|
| Applicant's or agent's file reference<br>116855  | <b>FOR FURTHER ACTION</b> See Form PCT/IPEA/416          |  |
| International application No.<br>PCT/SE 2003/001085  | International filing date (day/month/year)<br>23.06.2003 | Priority date (day/month/year)<br>20.06.2002 |
| International Patent Classification (IPC) or national classification and IPC<br>C08G 18/10, C08G 18/42, A61L 27/18 |  |  |
| Applicant<br>Artimplant AB et al   |  |  |

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 4 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
  - ☒ (sent to the applicant and to the International Bureau) a total of 2 sheets, as follows:
    - ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
    - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
  - ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) \_\_\_\_\_, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

- This report contains indications relating to the following items:

- |                                     |              |   |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report   |
| <input type="checkbox"/>            | Box No. II   | Priority  |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application   |

|   |  |
|---|--|
| Date of submission of the demand<br><br>08.01.2004  | Date of completion of this report<br><br>09.09.2004                          |
| Name and mailing address of the IPEA/SE<br>Patent- och registreringsverket<br>Box 5055<br>S-102 42 STOCKHOLM<br>Facsimile No. +46 8 667 72 88 | Authorized officer<br><br>Monika Bohlin/Els<br>Telephone No. +46 8 782 25 00 |

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))  
☐ publication of the international application (under Rule 12.4)  
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:

pages 1-37 \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☒ the claims:

pages \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ as amended (together with any statement) under Article 19

pages\* 39-40 received by this Authority on 01.09.2004

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ the drawings:

pages \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (*specify*): \_\_\_\_\_

☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (*specify*): \_\_\_\_\_

☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

|                               |        |             |     |
|-------------------------------|--------|-------------|-----|
| Novelty (N)                   | Claims | <u>1-12</u> | YES |
|                               | Claims |             | NO  |
| Inventive step (IS)           | Claims | <u>1-12</u> | YES |
|                               | Claims |             | NO  |
| Industrial applicability (IA) | Claims | <u>1-12</u> | YES |
|                               | Claims |             | NO  |

**2. Citations and explanations (Rule 70.7)**

This Preliminary Examination Report is based on the amended claims 1-12 filed with the letter of 04.09.01.

The claimed invention relates to a linear block copolymer and to fibres, films, porous materials and implants manufactured from the copolymer. In particular, the claimed copolymer is intended for use in anterior cruciate ligament (ACL) reconstruction. The claimed polymer is a poly(urethane urea) (PUUR) with optimised mechanical properties and degradation speed compared to similar, prior art copolymers.

The following documents, cited in the international search report, will be discussed:

D1 Macromol. Symp. 130 (1998) pp. 103-111

D2 J. of Mat. Sci., Materials in medicine, 13 (2002) pp. 351-359

D1 discloses PUUR-fibres having a tensile strength of up to 0.4 N/tex and elongation at break less than 40% (see page 108 first paragraph). These properties are within the scope of the present claims 6-8. Further according to D1, the low elongation is obtained by orienting the molecules as much as possible and shortening the length of the soft segment to about 500 g/mol (page 106, first paragraph). D1 does not specify what diisocyanate has been used in the synthesis, but one of the diols used is PCL-530, and the prepolymer is chain extended with an aliphatic diamine. The NCO:OH molar ratio is not specified.

D2 discloses mechanical tests performed on a PUUR intended for

.../...

## Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

ACL reconstruction. The PUUR was synthesised by the method described in D1. The diol used was PCL-530, the diisocyanate was 4,4'-diphenylmethane diisocyanate, and the chain extension was performed with 1,3-diaminopropane. The NCO:OH ratio was 2:1. Fibres were converted to yarns and woven into bands. Tensile tests were run on three bands, which resulted in a mean elongation at break of 89%.

D2 is considered to represent the closest prior art. The subject matter of the present claims 1-5 and 8 differs from D2 only in that the NCO:OH ratio should be larger than 2:1. In the examples 1, 2 and 4 of the present application the molar ratios used were 2.10:1, 2.04:1 and 2.05:1 respectively. The conclusions presented on page 33 of the present application are also disclosed in D2.

However, it is clear that the distinguishing feature gives rise to a non-obvious technical effect since the value of elongation at break is 89 % for the bands of linear block copolymer according to D2 compared to less than 44 % for the presently claimed copolymer.

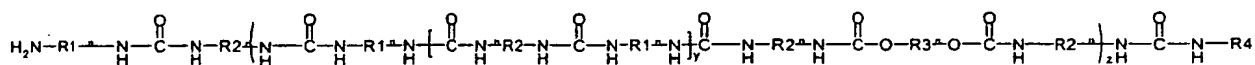
Although D1 discloses values of elongation at break less than 40 %, this document does not teach the use of aromatic isocyanate or a NCO:OH ratio larger than 2:1.

Accordingly, the invention according to claims 1-12 is considered to be novel, to involve an inventive step and to be industrially applicable.

## CLAIMS

1. Linear block polymer according to Formula (1)

5



(1)

10      Wherein

R1 is derived from a diamine, e.g. ethylene diamine, 1,2-diamino propane or 1,3-diamino propane;

15 R2 is derived from an aromatic diisocyanate;

R3 is derived from an esterdiol;

R4 is derived from dibutyl amine or ethanolamine;

20

Where  $0 < y < 4$  and  $z > 8$ ,

characterized in that,

25 the monomers from which R2 and R3 are derived from are added in such amounts that the molar ratio between R2 and R3 is larger than 2:1.

2. Linear block polymer according to claim 1, wherein R1 is derived from ethylene diamine, 1,3-diamino propane, 1,2-diamino propane, 1,4-diamino butane, 1,5-diamino pentane, or 1,6-diamino hexane.

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REPLACED BY  
ART 34 AMDT

3. Linear block polymer according to claim 1 or 2, wherein R3 is derived from polycaprolactone diol, polydiethylene glycol adipate or poly(pentane diolpimelate).
- 5 4. Linear block polymer according to any of the preceding claims, wherein R2 is derived from 4,4'diphenyl methane diisocyanate, naphthalene diisocyanate, or toluene diisocyanate.
5. Fibre manufactured from a linear block polymer according to any of the  
10 preceding claims.
6. Fibre according to claim 5, which fibre exhibits a toughness of at least 0.1 N/Tex.
- 15 7. Fibre according to claim 6, which fibre exhibits a toughness above 0.2 N/Tex.
8. Fibre according to any of claims 5-7 which fibre exhibits an elongation at break that is below 100 %.
- 20 9. Film manufactured from a linear block polymer according to any of the claims 1-4.
10. Porous polymeric material manufactured from a linear block polymer  
25 according to any of the claims 1-4.
11. Implant for the implantation into the human or animal body, which implant comprises a linear block polymer according to any of the preceding claims.